COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, ss.

SUPERIOR COURT
CIVIL ACTION NO. 11-3500

GERALD GENTILE, in his capacity as Administrator of the Estate of DIANE GENTILE, Deceased,

Plaintiff,

v.

BIOGEN IDEC, INC. and ELAN PHARMACEUTICALS, INC.,

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

2581E000009/30/11CIVIL 240.00
2581E000009/30/11SURCHARGE 15.00
2581E000009/30/11SECC 20.00
2581E000009/30/11SUMMONS 10.00

FILED
IN THE OFFICE OF THE
CLERK OF COURTS
FOR THE COUNTY OF MIDDLESEX
SEP 30 2011
CLERK

Plaintiff Gerald Gentile ("Plaintiff"), as duly appointed Representative of the Estate of Diane Gentile, by and through his undersigned attorney, hereby brings this wrongful death action for damages and other relief against Defendants BIOGEN IDEC, INC. and ELAN PHARMACEUTICALS, INC. (collectively, "Defendants") and alleges as follows:

I.
PARTIES

1. Plaintiff is a resident of Williamsville, New York. Plaintiff is the surviving spouse of Diane Gentile ("Ms. Gentile"), who died as a result of Tysabri® infusions manufactured by Defendants.

2. Plaintiff has been duly appointed by the Surrogate's Court of the State of New York as Administrator of the Estate of Ms. Gentile. Ms. Gentile's heirs-at-law include Plaintiff and the couple's children, Kristen and Nicholas Gentile (together, "the children").

3. Plaintiff brings this action in his representative capacity as Administrator of his wife's estate.

4. Defendant Biogen Idec, Inc. ("Biogen") is a Delaware corporation with a principal place of business at 133 Boston Post Road, Weston, Middlesex County, Massachusetts.

5. Defendant Elan Pharmaceuticals, Inc. ("Elan Pharma") is a corporation organized under the laws of the State of Delaware with a principal place of business at 800 Gateway Boulevard, South San Francisco, CA 94080. Defendant Elan Pharma is a wholly-owned subsidiary of Elan Corporation PLC ("Elan Corp.").

6. In August 2000, Defendant Biogen and Elan Pharma International Limited ("Elan Pharma Intl.") announced that they had entered into a joint collaboration agreement to bring Tysabri® to market. Tysabri®, generically known as natalizumab and formerly known as Antegren, is a potent immunosuppressant drug. The agreement required Defendant Biogen and Elan Pharma Intl. to share equally in the revenues and costs and to set up a number of joint teams. Both companies participated in the development of Tysabri®, including clinical trials, as well as the marketing of Tysabri®. The agreement also required that any information discovered by one company, including adverse events, be reported to the other company in a timely manner.

7. In May 2004, Biogen and Elan Corp. submitted a Biologics License Application ("BLA") to the FDA for approval of Tysabri® for the treatment of multiple sclerosis ("MS").

8. At all times relevant to this action, Defendant Elan Pharmaceuticals, Inc. was the registered trademark holder of, and distributor for Tysbari® in the United States.

II.
JURISDICTION AND VENUE

9. This Court has jurisdiction over Biogen pursuant to G.L. c. 223A, §2, because Biogen has its principal place of business in this Commonwealth. Biogen has purposefully availed itself of doing business in this Commonwealth under the protection of Massachusetts's laws, and the exercise of personal jurisdiction over Defendants in this county is proper.

10. This Court has jurisdiction over Elan Pharma pursuant to G.L. c. 223A, §3, because the Defendant has transacted business in this Commonwealth, contracted to supply services in this Commonwealth, and caused tortious injury by an act or omission in this Commonwealth.

11. Venue is proper because Biogen resides and transacts business in Middlesex County.

III.
FACTUAL BACKGROUND

12. In November 2004, the United States Food and Drug Administration ("FDA") approved Tysabri® for the treatment of remitting and relapsing MS. On or about November 24, 2004, Defendants began to market and distribute Tysabri® in the United States.

13. MS is a degenerative neurological disease characterized by recurrent episodes of inflammation in the white matter of the central nervous system ("CNS"). Surrounding and protecting the nerve fibers of the central nervous system is a fatty tissue called myelin, which helps nerve fibers conduct electrical impulses. The inflammation destroys the myelin sheath, a covering of the nerve cells leaving multiple areas of scar tissue

and adversely affecting CNS function.

14. Tysabri® is a monoclonal antibody that binds to a specific site on lymphocytes, interrupting cellular communication in the immune system. Tysabri® prevents lymphocytes from migrating from the bloodstream into the brain where they can cause inflammation and damage cells that insulate nerve fibers in MS patients. However, it is also believed that Tysabri® prevents white blood cells both from migrating to places in the body where they are needed, leaving a patient vulnerable to "opportunistic infections," which occur when ordinarily benign organisms infect individuals with impaired immune systems.

15. Since approximately 1992, Tysabri has been linked to one such opportunistic infection, Progressive Multifocal Leukoencephalopathy ("PML"). PML is a typically fatal brain disease caused by the immunosuppressive effects of Tysabri®. Specifically, PML is caused by JC virus, a strain of papovavirus ordinarily latent in the human kidney, replicating in the brains of individuals with impaired immune systems. PML manifests itself with symptoms such as impaired cognition, difficulty thinking, cortical blindness and weakness on one side of the body. PML usually results in death within one to four months of the onset of the disease, but some patients live years.

16. On or about October 23, 1996, Athena Neurosciences, Inc ("Athena") filed with the FDA an investigational new drug ("IND") application number BB-IND 6895 for Tysabri® (natalizumab). On or about July 1, 1996, Elan Pharma acquired Athena and all rights to the IND application number BB-IND 6895. On or about January 19, 1999, Athena notified the FDA that the IND application number BB-IND 6895 had been transferred to Elan Pharma.

17. In August of 2000, Biogen and Elan Pharma Intl entered into a

"Development and Marketing Collaboration Agreement" between Biogen, Inc. and Elan Pharma Intl (the "Agreement") under which Biogen and Elan Pharma Intl exchanged "worldwide royalty-free" co-exclusive licenses to develop, manufacture, distribute, and sell Tysabri®. The Agreement required the establishment of a Joint Steering Committee ("JSC"), comprised of three senior members of Biogen and Elan Pharma Intl, respectively, to oversee and manage a newly created Joint Project Team and Joint Commercialization Team ("Joint Project Team"). The JSC was required, among other things, "to ensure a regular flow of information between the parties."

18. Article 13.3 of the Agreement, was captioned ADVERSE DRUG EVENTS, and provided, in pertinent part, as follows:

> The Parties agree that the groups responsible for the safety surveillance and pharmacovigilance of the Licensed Product [including Tysabri] at each company shall meet within sixty (60) days following the Effective Date to develop detailed procedures regarding the format, timing and content of the safety information to be exchanged between the parties, and shall meet periodically thereafter to update the procedures.

19. In 1992, based on animal studies and other in vitro experiments, scientists who developed Tysabri® concluded that it was far too dangerous for use in humans. As mentioned above, individuals who take Tysabri® become susceptible to PML because Tysabri® suppresses the immune system. By suppressing the immune system, Tysabri® allows the JC virus, ordinarily latent in a patient's kidney, to travel to the brain via the bloodstream, where it begins uncontrolled replication.

20. Despite the above evidence, in May 2004 Biogen and Elan Corp. submitted a Biologics License Application ("BLA") to the FDA for approval of Tysabri® for the treatment of MS. The submission included one-year data from ongoing trials which Defendants refused to disclose to the public.

21. In February 2005, as a result of three reports of patients diagnosed with PML and two cases proving fatal, Tysabri® was withdrawn from the market and clinical trials were put on hold. A year later, in February 2006, Defendants conducted a clinical trial in which they reported no additional cases of PML. Consequently on June 5, 2006, the FDA permitted Tysabri® to come back on the market

22. The FDA's approval for the reintroduction of Tysabri® into the market restricted the drug's use to monotherapy for remitting and relapsing MS. To gain FDA approval for reintroducing Tysabri® on the market, Defendants developed the Tysabri Outreach: Unified Commitment to Health ("TOUCH") prescribing program. TOUCH requires every Tysabri® prescriber, infusion site, and MS patient receiving Tysabri® in the United States to enroll in the risk management program run by Defendant Biogen that monitors patients for any signs of PML.

23. In an interview with the Associated Press on or around July 24, 2008, Shane Cooke, Chief Financial Officer of Elan Corp., stated that "neurologists and their MS patients in North America and Europe were increasingly confident that Tysabri . . . was safe when used on its own." Cooke also said "the further we go (without any new PML cases), the more comfortable that people become and the more that patients demand to be put on Tysabri."

24. On July 30 and 31, 2008, Defendants announced two more cases of PML in patients who had taken Tysabri®. Although Defendant Biogen claimed that the first case of PML was reported to the company on July 30, 2008, upon information and belief, Plaintiffs allege that Defendants withheld material information about those two PML cases from the public for at least two months prior to their announcement. The first case of PML occurred

in a patient who had received Tysabri® monthly monotherapy for seventeen months. The second case of PML occurred in a patient who had received Tysabri® monthly monotherapy for fourteen months.

25. Plaintiff is informed and believes that Defendants withheld material information about twelve suspected PML cases linked to Tysabri®. Prior to July 24, 2008, those twelve cases were privately reported in the FDA's Adverse Event Reporting System ("AERS"), a computerized information database designed to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. At least two of those twelve cases were reported by doctors as early as May 2008, when Tysabri® was used as monotherapy.

26. On August 1, 2008, Defendants held a joint conference call to discuss the two confirmed cases they had announced publicly. Officials for Defendant Biogen refused to disclose or discuss the number of Tysabri® patients suspected to be afflicted with PML. Defendant Biogen spokeswoman Naomi Aoki declined to provide any more specifics about the suspected PML cases, stating that "we don't want to get into the whole business of discussing suspected cases."

27. Between October 29, 2008 and July 24, 2009, nine additional cases of PML were publicly reported by Defendant Biogen after treatment with Tysabri® monthly monotherapy for longer treatment duration.

28. Following the announcement on July 24, 2009, Defendants ceased sharing information about new cases with the public on their websites. Specifically, Defendant Biogen stated that any new cases would be reported by word of mouth to medical professional and patient groups. In September 2009, two more cases of PML were reported

in patients taking Tysabri®. One case was reported in the New England Journal of Medicine, and the other was reported by Ralf Gold of the Ruhr University Bochum in Germany, who presented the data at the European Committee for Treatment and Research in Multiple Sclerosis. Defendant Biogen refused to comment on or confirm the existence of those PML cases.

29. In November 2009, Defendants announced that they were updating the U.S. label for Tysabri® to reflect the increased risk of PML when the drug is taken over a longer period of time. Defendants knew and should have known for years prior to 2009 that the risk of developing PML increases significantly the longer Tysabri® is taken by a patient. Yet, Defendants failed to warn consumers and healthcare providers about that increased risk.

30. It was not until July 2010 that Defendants actually revised the U.S. label for Tysabri® to reflect the increased risk of developing PML with longer treatment duration. The revised U.S. label for Tysabri® states: "In patients treated with Tysabri®, the risk of developing PML increases with longer treatment duration . . . . There are no known interventions that can reliably prevent PML or adequately treat PML if it occurs. It is not known whether early detection of PML and discontinuation of TYSABRI will mitigate the disease." However, this warning is located in the warning and precautions part of the label, not in a black box warning.

31. By mid-January 2010, the number of confirmed cases of patients who developed PML after treatment with Tysabri® had risen to thirty-one.

32. In a letter dated March 25, 2010, the FDA notified Defendant Biogen's Senior Vice President of Regulatory Affairs that Defendant Biogen's promotion of Tysabri® contained "false or misleading" information. The letter explained that Defendant

Biogen's promotional information regarding Tysabri® "minimized important risks associated with the use of Tysabri and omits the drug's approved indication."

33. By February 2011, there were ninety-five confirmed cases of PML, including sixty-four within the past year. The number of deaths among those patients has risen to twenty.

34. Ms. Gentile was diagnosed with MS in 1981. Ms. Gentile's MS was characterized by muscle fatigue, dizziness, numbness, imbalance, and memory problems.

35. In approximately October 2006, Ms. Gentile's physician began to treat her MS with Tysabri® infusions.

36. Ms. Gentile received Tysabri® infusions on a monthly basis for three years. As of September 2009, Ms. Gentile underwent thirty-six treatments of Tysabri®.

37. In October 2009, Ms. Gentile began to develop cognitive difficulties that adversely affected her ability to talk and understand others. Additionally, she was experiencing problems with mobility. During an extended stay at the hospital from October 7, 2009 until October 16, 2009, doctors performed a MRI analysis which revealed a PML diagnosis. After being diagnosed with PML, Ms. Gentile discontinued all Tysabri® infusions.

38. Throughout the period that Ms. Gentile received Tysabri® infusions, Defendants gave no warning that there is an increased risk of developing PML with longer treatment duration.

39. Ms. Gentile was unable to survive the fatal disease of PML and died on December 15, 2009. Her death certificate named PML as a cause of death.

40. Following Ms. Gentile's death, Plaintiff and the children were distressed and suffered the loss of Ms. Gentile's love, care, compassion, and companionship.

41. Tysabri® is a product designed, formulated, manufactured, marketed, distributed, promoted, advertised, packaged, sold and/or supplied by Defendants that was placed into the stream of commerce by Defendants in a condition that was defective and unreasonably dangerous as designed taking into consideration the utility of the products and the risks involved in their use.

42. Tysabri® was unsafe for its intended and/or reasonably foreseeable purposes and uses at the time it was distributed, sold or supplied by Defendants because the known side effects and adverse consequences outweighed the benefits of the product. Tysabri® left Defendants' hands in this defective condition and caused Ms. Gentile to develop PML and the gravity of that damage outweighed the burden on Defendants to adopt an alternative design or method and the adverse effect of such alternative design or method on the utility of the drug.

43. At the time Tysabri® left the hands of Defendants, there were safer alternative designs that were economically and technologically feasible by the application of reasonable scientific knowledge.

44. The defectively designed condition of Tysabri® rendered the product unreasonably dangerous and defective for its intended and reasonably foreseeable uses, as those terms are understood in law, and was the producing and proximate cause of the injuries and damages sustained by Ms. Gentile and Plaintiff, for which Defendants are liable to Plaintiff.

45. At all relevant times, Defendants owed a duty to warn healthcare providers and patients adequately that, in patients being treated with Tysabri®, the risk of developing PML increases with longer treatment duration.

46. Tysabri® was unreasonably dangerous because, at the time the product left Defendants' control, there was no adequate warning regarding the increased risk of developing PML with longer treatment duration of Tysabri®, and Defendants failed to use reasonable care to provide an adequate warning of this danger to healthcare providers and patients. Defendants' failure in this regard is particularly egregious as patients taking Tysabri® are reluctant to stop using the drug because, when discontinued, the drug causes MS symptoms to become worse than prior to initial ingestion of the drug.

47. Ms. Gentile's development of PML and her resulting damages were proximately caused by Defendants' failure to warn her and her Tysabri® prescriber that, in patients being treated with Tysabri®, the risk of developing PML increases with longer treatment duration.

48. Defendants impliedly warranted to the public in general, to health care providers, including Ms. Gentile's physician, and to Ms. Gentile, that Tysabri® was merchantable and reasonably fit and suitable for the treatment of MS, and that it conformed to the standards imposed by law, and was safe and efficacious when used for MS.

49. Ms. Gentile relied on the skill and judgment and implied warranties of Defendants that Tysabri® was of merchantable quality and safe and fit for the treatment of MS. Ms. Gentile was a person whom Defendants might reasonably have expected to consume or be affected by Tysabri®.

50. Tysabri® was unsafe for its intended use, and was not of merchantable quality, as warranted by Defendants, in that it had very dangerous propensities when used for treatment of MS and caused severe injury to Ms. Gentile. Tysabri® was unaccompanied by adequate warnings of the risk of PML, either known or reasonably scientifically knowable at the time of distribution. Tysabri® caused Ms. Gentile to sustain injury and damages as herein alleged.

COUNT I
WRONGFUL DEATH
G.L. c. 229, § 2

51. Plaintiff incorporates all preceding paragraphs as if fully set forth herein and further alleges as follows:

52. Defendants are the manufacturers, designers, marketers, distributors, suppliers and sellers of Tysabri®.

53. Ms. Gentile's death was a direct and proximate result of Defendants' negligence in the design, development, research, manufacture, marketing, sales and distribution of Tysabri®.

54. Ms. Gentile's death was a direct and proximate result of Defendants' negligent failure to warn of the increased risk of developing PML with longer treatment duration of Tysabri®.

55. Defendants' conduct in the design, development, research, manufacture, marketing, sale and/or distribution of Tysabri® constituted willful, wanton or reckless acts, or gross negligence, which directly and proximately caused the death of Ms. Gentile under such circumstances that the deceased could have recovered damages for personal injuries if her death had not resulted.

56. Defendants' failure to warn of the increasing risk of developing PML with longer treatment duration of Tysabri® constituted willful, wanton or reckless acts, or gross negligence, which directly and proximately caused the death of Ms. Gentile under such circumstances that the deceased could have recovered damages for personal injuries if her death had not resulted.

57. Plaintiff and the children, as heirs-at-law, are entitled to recover damages for their loss of Ms. Gentile's services, protection, care, assistance, society, companionship, comfort, guidance, counsel, advice, as well as for loss of reasonably expected net income of Ms. Gentile.

58. Ms. Gentile's estate is entitled to recovery of reasonable medical, funeral and burial expenses, as well as recovery of punitive damages.

COUNT II.
CONSCIOUS SUFFERING
G.L. c. 229, § 6

59. Plaintiff incorporates all preceding paragraphs as if fully set forth herein and further alleges as follows:

60. As the direct and proximate result of Defendants' negligence, gross negligence, and/or willful, wanton or reckless acts further described above, Ms. Gentile was caused to suffer consciously from the time she first developed adverse symptoms in October 2009 until her death on December 15, 2009.

61. Ms. Gentile's estate is entitled to recover damages for her conscious suffering resulting from such bodily injuries.

WHEREFORE, Plaintiff demands judgment in his favor and against Defendants, jointly and severally, as follows:

a. Compensatory damages as allowed under G.L. c.229, §§ 2 and 6;

b. Punitive damages as allowed under G.L.c. 229, § 2;

c. Pre-judgment and post-judgment interest as allowable at law; and

d. Costs, interest, attorney's fees and such other relief as this Court may deem appropriate.

PLAINTIFF HEREBY DEMANDS A TRIAL BY JURY.

DATED: September 29, 2011

Respectfully submitted,

Fredric L. Ellis, BBO # 542075
Edward D. Rapacki, BBO # 411910
Joseph M. Makalusky, BBO # 631240
ELLIS & RAPACKI LLP
85 Merrimac Street
Suite 500
Boston, MA 02114
(617) 523-4800
(617) 523-6901

ATTORNEYS FOR PLAINTIFFS

Of Counsel

Edward Blizzard, Esq. (TBN 02495000)
440 Louisiana, Suite 1710
Houston, Texas 77002
telephone: (713) 844-3750
facsimile: (713) 844-3755
eblizzard@blizzardlaw.com
(*pro hac vice* admission will be requested)